JAN 17 2002

5. Summary of Safety and Effectiveness

5.1 Date of application: 06/26/2001

5.2 Applicant's name and address: H&C Medical Devices spa
Via Pisa 250
20099 Sesto San Giovanni
(Milan) ITALY

5.3 Contact person: Mr. Attilio Castelli
Tel: (+39) 0222476861
Fax: (+39) 0222476872
E-mail: attilio@hcmed.com

5.4 Device Trade Name
ecg@home

5.5 Device Common Name
ECG Transmitter, Electrocardiograph

5.6 Device Classification Name
CFR 870.2920 Transmitters and Receivers, Electrocardiograph, telephone
Class II 74 DXH

5.7 Predicate Device
The legally marketed device to which equivalence is being claimed is:

Manufacturer Name	Applicant Name	Predicate Device	510(k) Number
Card Guard 'Scientific Survival LTD	Card Guard LTD	CG-2206 Personal ECG Transmitter	K963725

Table 5.7.1 reports a tchnical comparison between ecg@home device and CG-2206 Predicate device.

Summary of Safety and Effectiveness (con't)

Table 5.7.1

Parameter	ecg@home	CG 2206
ECG INPUT AND PROCESSING		
Input dynamic range	+/-300mV @ DC +/-5 mV within the bandpass	+/-300mV @ DC +/-2.5 mV within the bandpass
Input Impedance	10 Mohm	100 Mohm
CMRR	> 100 dB	60 dB
Frequency response	0.5 – 30 Hz (-3dB) (linear phase)	0.5 – 40 Hz (-3dB)
A/D conversion	11 bits	8 bits
Sampling frequency	500 samples/s	250 samples/s
Leads	1 Standard lead D1 or D2	1 non Standard chest lead
Mode of operation	Patient activated recording	Patient activated recording
Memory	10 s (200 s optional)	192 s
Display	LCD	N/a
Clock	Yes (optional)	N/a
ACUSTIC TRANSMISSION		
Type	Frequency Modulation	Frequency Modulation
Carrier frequency	1900 Hz	1700 Hz
Modulation factor	100 Hz/mV	170 Hz/mV
DIGITAL INTERFACE		
	RS 232 serial digital port	N/a
POWER SUPPLY		
Battery type	2 x 1.5V AAA (IEC LR03)	2 x 3V lithium
Autonomy	2400 recordings	2000 recordings
MECHANICAL		
Size	4.13 x 3.15 x 0.59 in	4.13 X 2.16 X 0.39 in
Weight	100 gr	42 gr
Operating temperature	+50...+113 °F	32...+113 °F
Storage temperature	+32...+122 °F	-4...+122 °F

5.8 Device description

Ecg@home is a personal single lead ECG transtelephonic transmitter characterized by the following features:

- Internal battery operation
- Patient activated acquisition of Standard lead D1 (lead D2 by means of an external auxiliary electrode)
- Storage of 10 seconds of acquired ecg signal
- Use of two built-in "thumb electrodes" (**US Pat. N° 5,928,141**)

Summary of Safety and Effectiveness (con't)

- LCD display featuring the following characteristics:
  - Indication of the battery charge status
  - Indication that signal acquisition is active
  - Indication that a noisy acquisition has been performed
  - Indication that data transmission is active
  - Indication that the recording is stored in memory
  - Indication of the istantaneous and of the mean heart rate frequency

- Digital ecg transfer via RS232 serial digital port to a computer
- Acustic transtelephonic ecg transfer via common phone line

The use of two built-in patented electrodes allows the patient to record the electrocardiogram lead D1 by simply placing his thumbs on the electrodes.
The two patented electrodes are designed in such a way to minimize noise and base-line shifts due to relative movements at the electrode/skin interface.

5.9 Intended use

The device is intended for use by patients who might experience transient symptoms that may suggest cardiac arrythmia, conduction ECG abnormalities or other ECG abnormalities visibles on lead D1 or lead D2.
The device is not intended for the simultaneous recording and transmission of the patient's ECG signal.
ECG acquisition and transmission is voluntary and manually activated by the patient.

5.10 Comparison of technological characteristics

ecg@home personal electrocardiogram transmitter is based on technological characteristics similar to the predicate device CG – 2206.

5.11 Non clinical tests used for Substantial Equivalence Determination

Full safety tests according to EN60601-1 Standard and performances tests according to IEC 601-2 47 draft Standard have been performed on ecg@home.
The equipment have been subject to Electromagnetic Compatibility testing procedures according to EN60601-1-2 standard.
No adverse working conditions have been claimed and filed up to date.

Summary of Safety and Effectiveness (con't)

A similar version of the device is CE marked according to 93/42/CEE Medical Device Directive.

5.12 Clinical tests performed

A set of in vivo clinical tests have been performed in order to asses the performances of the device. Tests were performed at the Medical University School of Brescia (Italy). Tests results have shown that the recordings performed on the patients using the device where highly satisfactory and comparable to those obtained with a common electrocardiograph recorder.

5.13 Conclusions

Based on the above, H&C Medical Devices belives that ecg@home personal electrocardiogram transmitter is substantially equivalent to Predicate device CG – 2206.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2002

Mr. Attilio Castelli
Managing Director
H&C Medical Devices spa
Via Pisa 250
20099 Sesto San Giovanni (Milan)
ITALY

Re: K012012
Trade Name: ecg @ home
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitters and Receivers
Regulatory Class: Class II (two)
Product Code: DXH
Dated: October 22, 2001
Received: October 25, 2001

Dear Mr. Castelli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

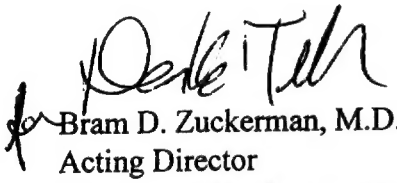
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K012012

4. Indications for Use Statement

Device Name: ecg@home

Indication for Use:

ecg@home is a personal single lead ECG transtelephonic transmitter. The device is intended for self-testing by patients by recording ten seconds of the first standard lead (D1) or of the second standard lead (D2) of the electrocardiogram. The recording is activated by the patient when symptoms are experienced or whenever desired as routine recordings to be analyzed by a trained physician.

The patient is normally not required to apply electrodes on the body. Two electrodes integrated within the device are provided. The patient has to place his thumbs on the two integrated electrodes in order to record the ECG signal.

In case of very low amplitude of lead D1 caused by heart orientation (mainly experienced by women), an external auxiliary electrode is provided in order to record lead D2.

The recorded data can be directly trasmitted to a receiving station via a common phone line or can be downloaded via RS 232 serial digital port to a Personal Computer for subsequent connection to a Service Provider using Internet facilities.

Prescription Use X
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) number K012012